

## **TITLE 16. Board of Pharmacy**

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 5, 2004.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Department of Consumer Affairs, 400 R Street, Sacramento, CA 95814 at 1:30 p.m. on April 21, 2004.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 4005 of the Business and Professions Code and to implement, interpret or make specific Sections 4081, 4113, 4305, 4330, 4331 and 4332 of the Business and Professions Code the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 4081 of the Business and Professions Code specifies that the pharmacy owner and the pharmacist-in-charge are jointly responsible for maintaining records relating to the acquisition and disposition of dangerous drugs and dangerous devices and maintaining a current inventory of dangerous drugs and dangerous devices for three years. This section also specifies that both the pharmacy owner and the pharmacist-in-charge are jointly responsible for making these records available to authorized officers of the law.

Section 4113 of the Business and Professions Code requires each pharmacy to designate a pharmacist as "pharmacist-in-charge" and to notify the Board of Pharmacy of that designation within 30 days. This section also specifies that the pharmacist-in-charge is responsible for the pharmacy's compliance with state and federal law. This section also requires each pharmacy to notify the board within 30 days when a pharmacist ceases to be the pharmacist-in-charge.

Section 4305 of the Business and Professions Code specifies that failure to notify the Board of Pharmacy of the termination of a pharmacist-in-charge within 30 days is grounds for disciplinary action. This section also specifies a pharmacy that willfully fails to notify the board of the termination of a pharmacist-in-charge and permits the continued operation of the pharmacy without

a pharmacist-in-charge is subject to summary suspension or revocation of the pharmacy license. This section also specifies that a pharmacist's failure to notify the board of their hiring or firing as pharmacist-in-charge within 30 days is grounds for disciplinary action.

Section 4330 specifies that a pharmacy that fails to designate a pharmacist-in-charge is guilty of a misdemeanor. This section also specifies that a non-pharmacist owner of a pharmacy who interferes with a pharmacist-in-charge's efforts to lawfully operate a pharmacy is guilty of a misdemeanor.

Section 1709.1 of Title 16 of the California Code of Regulations does the following:

1. Requires the pharmacist-in-charge to be employed at the pharmacy and be responsible for its daily operation.
2. Prohibits a pharmacist from acting pharmacist-in-charge at a more than one pharmacy.
3. Prohibits a pharmacist from acting as a pharmacist-in-charge in a pharmacy and a wholesaler, medical device retailer, or veterinary food-animal drug retailer.
4. Permits a pharmacy to designate an interim pharmacist-in-charge who does not work at that pharmacy.
5. Prohibits an interim pharmacist-in-charge to serve for more than 120 days.

This notice proposed to amend Section 1709.1 as follows:

1. Require a pharmacy owner to vest the pharmacist-in-charge with sufficient authority to allow the pharmacist-in-charge to comply with the law.
2. Permit a pharmacist to serve as pharmacist-in-charge at two pharmacies located within 50 miles of each other.
3. Permit a pharmacist to decline to serve as pharmacist-in-charge at a second pharmacy under specified circumstances.
4. Prohibit a pharmacy from disciplining a pharmacist who declines to serve as a pharmacist-in-charge at a second pharmacy.

The Board of Pharmacy has proposed this amendment to Section 1709.1 to further clarify the role of the pharmacist-in-charge and to permit a pharmacist to serve as pharmacist-in-charge at two pharmacies.

#### FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action

would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not adversely affect small businesses. The Board of Pharmacy made this determination because the proposed regulation would provide pharmacies with more flexibility when designating the pharmacist-in-charge.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website

([www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)).

**AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE**

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

**CONTACT PERSON**

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Paul Riches
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4016
Fax No.:	(916) 327-6308
E-Mail Address:	Paul_Riches@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x4005
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E-Mail Address:	Virginia_Herold@dca.ca.gov

**Website Access:** Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).